



This is provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Pilkul 400

(Food for Specified Health Uses)

Food Safety Commission of Japan (FSCJ)
March 2020

SUMMARY

FSCJ conducted a risk assessment of pilkul 400 as a food for specified health uses, which aim to maintain the digestive function healthy, based on the documents submitted by the applicant. This product contains *Lactobacillus paracasei* subsp. *paracasei* NY1301 as the relevant ingredient.

In a 65 ml of this product, corresponding to the recommended daily intake, more than 4.0×10^{10} cfu of *L. paracasei* subsp. *paracasei* NY1301 is contained.

The assessed data include history of use as the food, a 4-week repeated oral dose toxicity study in rats, and human studies such as 2-week continuous consumption test on people with constipation tendency, 12-week continuous consumption and 4-week three-fold excessive consumption in healthy people, and other studies.

FSCJ concluded, from the above results, that pilkul 400 has no obvious risk to human health as far as the documents submitted by the applicant were concerned.